IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Atty. Dkt. No 054707-0185

Applicant: Joseph P. STEINER et al.

Title: NOVEL PYRROLIDINE CARBOXYLATE HAIR REVITALIZING AGENTS

Appl. No.: 09/825,896

Filing Date: 04/05/2001

Examiner: Rebecca Cook

Art Unit: 1614

APPEAL BRIEF TRANSMITTAL

Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicant hereby submits to the Board of Appeals three copies of an Appeal Brief which follow the Notice of Appeal filed June 20, 2002.

The items checked below are appropriate:

1 **XX** Appeal Brief with the Small-Entity Fee $160.00 (in triplicate);

2. **XX** Petition for Extension of Time with Fee $145.00;[1] and

[1] A petition for an Extension of Time was filed August 22, 2002, to extend the time for response from August 20, 2002, to September 20, 2002. With that petition, the fee of $55 under 37 C.F.R. § 1.17(a)(1) was paid. Thus, the present petition extends the period for response from September 20, 2002, to October 20, 2002. The enclosed check covers the difference in fee between a two-month Extension of Time under 37 C.F.R. § 1.17(a)(2) and the previously-paid-one-month extension of time under 37 C.F.R. § 1.17(a)(1).

3. XX A check in the total amount of $305. 00 is enclosed for the Appeal Brief fee and Petition for Extension of Time. The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 19-0741.

Respectfully submitted,

Date 10/21/2

By _____

Sean A. Passino
Attorney for Applicant
Registration No. 45,943

FOLEY & LARDNER
Customer Number: 29728
29728
PATENT TRADEMARK OFFICE
Telephone: (202) 295-4166
Facsimile: (202) 672-5399

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APPEAL BRIEF UNDER 37 C.F.R. § 1.192

This brief answers the final Office Action of February 20, 2002. It is filed with two additional copies of the originally signed brief. It is accompanied by the small-entity fee of $160 under 37 C.F.R. § 1.17(c). It is timely, since it is filed within four months of the Notice of Appeal dated June 20, 2002, and is accompanied by a Petition for an additional-month Extension of Time and the fee of $145, which is the difference between the fees under 37 C.F.R. §§ 1.17(a)(2) and (a)(1).[1]

1. Real Party Interest

GPI NIL Holdings Inc. is the real party in interest.

[1] A petition for an Extension of Time was filed August 22, 2002, to extend the time for response from August 20, 2002, to September 20, 2002. With that petition, the fee of $55 under 37 C.F.R. § 1.17(a)(1) was paid. Thus, the present petition extends the period for response from September 20, 2002, to October 20, 2002. The enclosed check covers the difference in fee between a two-month Extension of Time under 37 C.F.R. § 1.17(a)(2) and the previously-paid-one-month extension of time under 37 C.F.R. § 1.17(a)(1).

2. Related App als and Int rf r nces

Appellant, Appellant's legal representative, and Assignee know of no other appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

3. Status Of Claims

Claims 6-8, 10-12, 14-16, 18-20, and 22-27 are pending. Claims 1-5, 9, 13, 17, and 21 are cancelled. Claims 25-27 are appealed.

4. Status Of Amendments

All amendments were entered.

5. Summary Of Invention

The present invention regards a pharmaceutical composition comprising an effective amount of a specified compound, a second hair revitalizing compound, and a pharmaceutically acceptable carrier. Specification, p. 14, ll. 5-10; p. 15, ll. 8-9.

6. Issues

There is one issue presented for review:

A. whether claims 25-27 are patentable under 35 U.S.C. § 101 (double patenting) in view of claims 22-24 of U.S. Patent No. 6,239,164.

7. Grouping Of Claims

For the purpose of this appeal only, the claims stand or fall together for the ground of rejection which Appellant contests and which applies to a group of two or more claims.

8. Argument

A. The statutory double patenting rejection of claims 25-27 over claims 22-24 of U.S. Patent No. 6,239,164 is improper and should be reversed, because each set of claims differs in scope.

An improper statutory double patenting rejection is made when the "same invention" is not claimed by two sets of claims. MPEP § 804 II. A. Nonidentical inventions may be identified by spotting embodiments that are excluded from one set of claims but not the other. Id.

Nonidentical inventions are claimed here, since the present claims embrace more embodiments in at least one aspect than the claims of the '164 patent. Specifically, a relevant part of present claim 25 reads as follows: "an effective amount of a compound of formula I." On the other hand, a relevant part of the '164 patent's claim 21, from which claims 22-24 depend, reads as follows: "an effective amount of a *non-immunosuppressive* pyrrolidine carboxylate or pyrrolidine amide compound *having an affinity for FKBP-type immunophilins*." (Emphasis added). Embodiments that are excluded from the '164 patent's claims 22-24 but not present Application's claims 25-27 are believed apparent from the broadest reasonable interpretation of these claims. Cf. MPEP § 2111. Thus, the present claims are nonidentical face-to-face the claims of the '164 patent.

The Examiner, however, cited page 4 of the present specification and urged that the missing-functional elements are inherent properties of the recited compounds. Office action of February 20, 2002, p. 2, ll. 16-19 (e.g., "the instant compounds ... have an affinity for FKBP-type immunophilins"). It is believed that the evidence and explanation of record is insufficient to establish a prima facie case of inherency, as inherency cannot be based upon probability or speculation. Thus, the rejection is improper and should be reversed.

9. Appendix

An appendix containing a copy of the claims involved in the appeal is attached.

10. Conclusion

The rejection should be reversed and the application allowed.

Respectfully submitted,

Date 10/21/2 By _____

FOLEY & LARDNER
Customer Number: 22428

22428

PATENT TRADEMARK OFFICE
Telephone: (202) 295-4166
Facsimile: (202) 672-5399

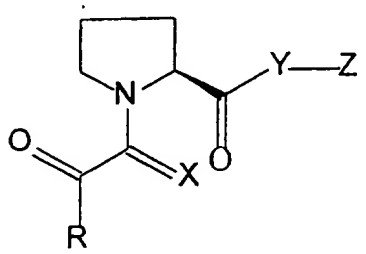
Sean A. Passino
Registration No. 45,943

If any [further] extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 19-0741.

APPENDIX

25. A pharmaceutical composition comprising:

(i) an effective amount of a compound of formula I:



I

or a pharmaceutically acceptable salt or hydrate thereof,

wherein

R is selected from the group consisting of a C_1-C_9 straight or branched chain alkyl or C_2-C_9 straight or branched chain alkenyl, C_3 or C_5 cycloalkyl, C_5-C_7 cycloalkenyl, and Ar_1,

wherein said alkyl or alkenyl is optionally substituted with C_3-C_8 cycloalkyl, C_1-C_4 alkyl, C_2-C_4 alkenyl, or hydroxy,

wherein said cycloalkyl or cycloalkenyl is optionally substituted with C_1-C_4 alkyl, C_2-C_4 alkenyl, or hydroxy,

Ar_1 is selected from the group consisting of 1-naphthyl, 2-naphthyl, 2-indolyl, 3-indolyl, 2-furyl, 3-furyl, 2-thiazolyl, 2-thienyl, 3-thienyl, 2-pyridyl, 3-pyridyl, 4-pyridyl, and phenyl,

wherein said Ar_1 has one to three substituents which are independently selected from the group consisting of hydrogen, halo, hydroxyl, nitro,

trifluoromethyl, C_1-C_6 straight or branched alkyl or C_2-C_6 straight or branched alkenyl, C_1-C_4 alkoxy or C_2-C_4 alkenyloxy, phenoxy, benzyloxy, and amino;

X is selected from the group consisting of oxygen, sulfur, methylene, and H_2;

Y is selected from the group consisting of oxygen and NR_2, where R_2 is hydrogen or C_1-C_6 alkyl; and

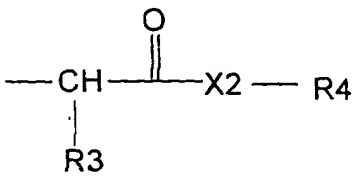
Z is selected from the group consisting of C_2-C_6 straight or branched chain alkyl or C_2-C_6 straight or branched chain alkenyl, and Ar_2,

wherein the C_2-C_6 straight or branched alkyl is substituted in one or more positions with Ar_1 as defined above, C_3-C_8 cycloalkyl, or cycloalkyl connected by a C_1-C_6 alkyl or C_2-C_6 alkenyl;

Ar_2 is selected from the group consisting of 2-indolyl, 3-indolyl, 2-furyl, 3-furyl, 2-thiazolyl, 2-thienyl, 3-thienyl, 2-pyridyl, 3-pyridyl, 4-pyridyl, and phenyl,

wherein said Ar_2 has one to three substituents which are independently selected from the group consisting of hydrogen, halo, hydroxyl, nitro, trifluoromethyl, C_1-C_6 straight or branched alkyl or C_2-C_6 straight or branched alkenyl, C_1-C_4 alkoxy or C_2-C_4 alkenyloxy, phenoxy, benzyloxy, and amino;

or Z is a fragment having the following formula:



wherein

R_3 is a C_1-C_9 straight or branched alkyl or unsubstituted Ar_1, wherein said C_1-C_9 straight or branched alkyl is optionally substituted with C_3-C_8 cycloalkyl or Ar_1 as defined above;

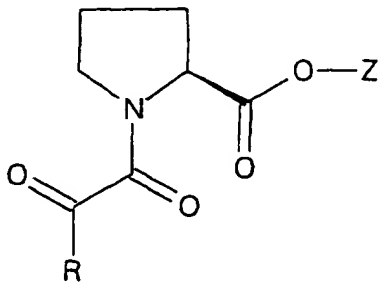
X_2 is O or NR_5, where R_5 is selected from the group consisting of hydrogen, C_1-C_6 straight or branched alkyl, and C_2-C_6 straight or branched alkenyl; and

R_4 is selected from the group consisting of phenyl, benzyl, C_1-C_5 straight or branched alkyl or C_2-C_5 straight or branched alkenyl, and C_1-C_5 straight or branched alkyl or C_2-C_5 straight or branched alkenyl substituted with phenyl;

(ii) a second hair revitalizing compound; and

(iii) a pharmaceutically acceptable carrier.

26. The pharmaceutical composition of claim 25 wherein the compound is of formula II:



II

or a pharmaceutically acceptable salt or hydrate thereof,

wherein

R is a C_1-C_9 straight or branched chain alkyl or C_2-C_9 straight or branched chain alkenyl C_3 or C_5 cycloalkyl, C_5-C_7 cycloalkenyl, or Ar_1,

wherein said C_1-C_9 straight or branched chain alkyl or C_2-C_9 straight or branched chain alkenyl is optionally substituted with C_3-C_8 cycloalkyl, C_1-C_4

alkyl, C_2-C_4 alkenyl, or hydroxy,

wherein said cycloalkyl or cycloalkenyl is optionally substituted with C_1-C_4 alkyl, C_2-C_4 alkenyl, or hydroxy;

Ar_1 is selected from the group consisting of 1-naphthyl, 2-naphthyl, 2-indolyl, 3-indolyl, 2-furyl, 3-furyl, 2-thiazolyl, 2-thienyl, 3-thienyl, 2-pyridyl, 3-pyridyl, 4-pyridyl, and phenyl,

wherein said Ar_1 has one to three substituents which are independently selected from the group consisting of hydrogen, halo, hydroxyl, nitro, trifluoromethyl, C_1-C_6 straight or branched alkyl or C_2-C_6 straight or branched alkenyl, C_1-C_4 alkoxy or C_2-C_4 alkenyloxy, phenoxy, benzyloxy, and amino;

Z is a C_2-C_6 straight or branched chain alkyl or C_2-C_6 straight or branched chain alkenyl, C_3-C_8 cycloalkyl, cycloalkyl connected by a C_1-C_6 alkyl or C_2-C_6 alkenyl, or Ar_2,

wherein said C_2-C_6 straight or branched alkyl chain is substituted in one or more positions with Ar_1,

Ar_2 is selected from the group consisting of 2-indolyl, 3-indolyl, 2-furyl, 3-furyl, 2-thiazolyl, 2-thienyl, 3-thienyl, 2-pyridyl, 3-pyridyl, 4-pyridyl, and phenyl,

wherein said Ar_2 has one to three substituents which are independently selected from the group consisting of hydrogen, halo, hydroxyl, nitro, trifluoromethyl, C_1-C_6 straight or branched alkyl or C_2-C_6 straight or branched alkenyl, C_1-C_4 alkoxy or C_2-C_4 alkenyloxy, phenoxy, benzyloxy, and amino.

27. The pharmaceutical composition of claim 25 wherein the compound is selected from the group consisting of:

3-phenyl-1-propyl (2S)-1-(3,3-dimethyl-1,2-dioxopentyl)-2-pyrrolidinecarboxylate,

3-phenyl-1-prop-2-(E)-enyl (2S)-1-(3,3,-dimethyl-1,2-dioxopentyl)-2-pyrrolidinecarboxylate,

3-(3,4,5-trimethoxyphenyl)-1-propyl (2S)-1-(3,3-dimethyl-1,2-dioxopentyl)-2-pyrrolidinecarboxylate,

3-(3,4,5-trimethoxyphenyl)-1-prop-2-(E)-enyl (2S)-1-(3,3-dimethyl-1,2-dioxopentyl)-2-pyrrolidinecarboxylate,

3-(4,5-methylenedioxyphenyl)-1-propyl (2S)-1-(3,3, dimethyl-1,2-dioxopentyl)-2-pyrrolidinecarboxylate,

3-(4,5-methylenedioxyphenyl)-1-prop-2-(E)-enyl (2S)-1-(3,3-dimethyl-1,2-dioxopentyl)-2-pyrrolidinecarboxylate,

3-cyclohexyl-1-propyl (2S)-1-(3,3-dimethyl-1,2-dioxopentyl)-2-pyrrolidinecarboxylate,

3-cyclohexyl-1-prop-2-(E)-enyl (2S)-1-(3,3-dimethyl-1,2-dioxopentyl)-2-pyrrolidinecarboxylate,

(1R)-1,3-diphenyl-1-propyl (2S)-1-(3,3-dimethyl-1,2-dioxopentyl)-2-pyrrolidinecarboxylate,

3-phenyl-1-propyl (2S)-1-(1,2-dioxo-2-[2-furanyl])ethyl-2-pyrrolidinecarboxylate,

3-phenyl-1-propyl (2S)-1-(1,2-dioxo-2-[2-thienyl])entyl-2-pyrrolidinecarboxylate,

3-phenyl-1-propyl (2S)-1-(1,2-dioxo-2-[2-thiazolyl])ethyl-2-pyrrolidinecarboxylate,

3-phenyl-1-propyl (2S)-1-(1,2-dioxo-2, phenyl)ethyl-2-pyrrolidinecarboxylate,

3-(2,5-dimethoxyphenyl)-1-propyl (2S)-1-(3,3-dimethyl-1,2-dioxopentyl)-2-pyrrolidinecarboxylate,

3-(2,5-dimethoxyphenyl)-1-prop-2-(E)-enyl (2S)-1-(3,3-dimethyl-1,2-dioxopentyl)-2-pyrrolidinecarboxylate,

2-(3,4,5-trimethoxyphenyl)-1-ethyl (2S)-1-(3,3-dimethyl-1,2-dioxopentyl)-2-pyrrolidinecarboxylate,

3-(3-Pyridyl)-1-propyl (2S)-1-(3,3-dimethyl-1,2-dioxopentyl)-2-pyrrolidinecarboxylate,

3-(2-Pyridyl)-1-propyl (2S)-1-(3,3-dimethyl-1,2-dioxopentyl)-2-pyrrolidinecarboxylate,

3-(4-Pyridyl)-1-propyl (2S)-1-(3,3-dimethyl-1,2-dioxopentyl)-2-pyrrolidinecarboxylate,

3-phenyl-1-propyl (2S)-1-(2-cyclohexyl-1,2-dioxoethyl)-2-pyrrolidinecarboxylate,

3-phenyl-1-propyl (2S)-1-(2-*tert*-butyl-1,2-dioxoethyl)-2-pyrrolidinecarboxylate,

3-phenyl-1-propyl (2S)-1-(2-cyclohexylethyl-1,2-dioxoethyl)-2-pyrrolidinecarboxylate,

3-(3-Pyridyl)-1-propyl (2S)-1-(2-cyclohexylethyl-1,2-dioxoethyl)-2-pyrrolidinecarboxylate,

3-(3-Pyridyl)-1-propyl (2S)-1-(2-*tert*-butyl-1,2-dioxoethyl)-2-pyrrolidinecarboxylate,

3,3-diphenyl-1-propyl (2S)-1-(3,3-dimethyl-1,2-dioxopentyl)-2-pyrrolidinecarboxylate,

3-(3-Pyridyl)-1-propyl (2S)-1-(2-cyclohexyl-1,2-dioxoethyl)-2-pyrrolidinecarboxylate,

3-(3-Pyridyl)-1-propyl (2S)-N-([2-thienyl]glyoxyl) pyrrolidinecarboxylate,

3,3-Diphenyl-1-propyl (2S)-1-(3,3-dimethyl-1,2-dioxobutyl)-2-pyrrolidinecarboxylate,

3,3-Diphenyl-1-propyl (2S)-1-cyclohexylglyoxyl-2-pyrrolidinecarboxylate, and

3,3-Diphenyl-1-propyl (2S)-1-(2-thienyl)glyoxyl-2-pyrrolidinecarboxylate,

or a pharmaceutically acceptable salt, hydrate, or mixture thereof.